

REMARKS

The Examiner has rejected claims 2-5 and 8 under U.S.C. § 103(a) over Miyamoto (US 5962535) in combination with Faour (US 6004582). The Applicants respectfully disagree with the Examiner and request that the rejection of the claims be withdrawn for the following reasons.

The Examiner indicates that Miyamoto teaches a combination of idebenone and an acetylcholinesterase inhibitor. Miyamoto, et al. do not provide an enabling disclosure for a sustained release formulation that teaches the Applicants invention. While, Miyamoto et al., in column 11 lines 5 – 10, suggest that the combination claimed may be provided in a sustained release composition, Miyamoto, et al. state that the dosage forms may be manufactured by known, *per se*, technology. However, Miyamoto do not provide examples of any sustained release formulations.

The Specification of the Applicants' present disclosure in Examples 1 through 7 provide an enabling disclosure of the claimed invention. In accord with the Examples, the Applicants' present invention identifies and claims specific release parameters. For example, claim 5 of the Applicants' claimed invention is directed to a pharmaceutical composition which has a core of drug from which an effective dose of drug is released 6 to 12 hours after ingestion. Claim 8 is directed to a two-pulse pharmaceutical composition wherein a first rivastigmine containing component of the releases 70 – 95% of rivastigmine from the component in 3-4 hours. Claim 4 is directed to a pharmaceutical composition wherein the coating of the composition has a thickness of 50 – 800 micrometers. These claims identify that the Applicants' invention has been determined to provide a unique release pattern for a controlled release composition of rivastigmine which is not taught or suggested by Miyamoto or the prior art. The fact that Miyamoto makes a vague reference to sustained release formulations, for which there is no enablement in the reference, does not provide a reference which teaches the applicants' invention.

Faour et al. teach an osmotic device but do not provide examples of a drug release pattern for any drug that could be used in the device. The examples in Faour disclose and teach only methods of manufacture of the invention therein. The disclosure of Faour does not provide a composition or methods which will lead to a controlled release formulation of rivastigmine that provides the type of release as claimed by the Applicants.

Thus the Applicants respectfully contend that nothing in the combination of the references, Miyamoto, et al. and Faour, et al. would motivate or suggest to one skilled in the art to create the controlled release formulations of rivastigmine that are claimed by the Applicants.

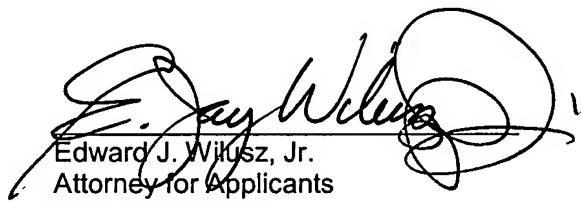
Therefore, based in the foregoing, the Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 103(a) over Miyamoto in view of Faour.

The Applicants believe that the case is now in condition for allowance and respectfully request early notice to that effect.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-0134 in the name of Novartis Corporation.

If it will advance prosecution of the case the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,



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